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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,079	08/01/2006	Edith Sorensen	P30006	3993

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EXAMINER	
KENNEDY, NICOLETTA	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
02/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/582,079	SORENSEN, EDITH	
	Examiner	Art Unit	
	Nicoletta Kennedy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-29* is/are pending in the application.

4a) Of the above claim(s) *16-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15 and 22-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/4/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1 and 3-29 are currently pending. Claims 16-21 are withdrawn as drawn to a non-elected group.

Priority

This application, filed June 8, 2006, is a national stage entry of PCT/EP04/13963, filed December 8, 2004. PCT/EP04/13963 is a continuation in part of PCT/EP03/13873, filed December 8, 2003.

Reopening of Prosecution after Appeal

In view of the Appeal Brief filed on November 30, 2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

New Rejections

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3-4, 6, 8, 11-13 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (translation, WO 97/19668) (pub. June 5, 1997) in view of Vellekoop et al. (US 4,765,984) (issued Aug. 23, 1988).

Regarding claims 1, 3-4, 6, 8, 11-13 and 22, Tame-Said teach a toothpaste and mouthwash in tablet (lozenge) form which dissolve in the mouth when contacted with saliva (abstract). The lozenge is comprised of 18 mg ascorbic acid (5.2% by weight), 50 mg sodium bicarbonate (14.49% by weight), 40 mg tricalcium phosphate (11.59% by weight), 17 mg sodium lauryl sulfate, 70 mg arabic gum (water soluble lozenge base)

and 150 mg natural sweetness and flavoring agents (abstract). Tricalcium phosphate is identified as a polishing and bleach agent (p. 5). However, Tame-Said fail to teach that calcium pyrophosphate is the polishing agent used in the tablet or that the amount of polishing agent may be modified. Vellekoop et al. cure this deficiency.

Vellekoop et al. teach oral products that may be in the form of a lozenge (title, abstract and column 3, lines 36-39). The oral product may contain water-insoluble polishing agents in an amount of about 5-25% (column 5, lines 55-66). Typical polishing agents include tricalcium phosphate and calcium pyrophosphate (column 5, lines 55-660.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Tame-Said with those of Vellekoop et al. to have substituted calcium pyrophosphate for tricalcium phosphate. One would have been motivated to do so because both tricalcium phosphate and calcium pyrophosphate are known polishing materials used in the dentrifice art in lozenges and Tame-Said teaches the use of tricalcium phosphate, a polishing agent, in the lozenge.

Regarding claims 1, 3 and 22, MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, Vellekoop et al. teach that it is known in the dentifrice art to have polishing agents present from about 5-25% by weight.

4. **Claims 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (abstract, WO 97/19668) (pub. June 5, 1997) in view of Bauman (US 3,928,618) (issued Dec. 23, 1975) as applied to claims 1, 3-4, 6, 8, 11-13 and 22 above, and further in view of Holme et al. (US 6,685,916) (filed Oct. 31, 2002.**

The combination of Tame-Said and Bauman teach each limitation of claim 1 but fail to teach that the lozenge may be sugarless, comprises an encapsulated agent, or is in the form of a hard-boiled lozenge. Holme et al. cure these deficiencies.

Regarding claim 5, Holme et al. teach a composition for removing stains from dental surfaces. The composition may be a confectionary including lozenges (column 3, lines 47-53). The sweetener used in the confectionary may comprise sugar or be sugarless and instead use sugarless sweeteners such as sorbitol, mannitol, xylitol and maltitol (column 10, lines 33-41 and column 12, lines 9-15).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Tame-Said and Bauman with those of Holme et al. to substitute sugarless sweetener for sugar in the composition. One would have been motivated to do so because using sugarless sweeteners reduces the amount of calories in the lozenge and does not contribute to the formation of dental plaque.

Regarding claim 10, Holme et al. teach that the composition may comprise encapsulated peroxide (claims 1 and 27). The peroxide is the active ingredient in the composition (abstract). It would have been prima facie obvious to a person of of

ordinary skill in the art at the time of the invention to have encapsulated the active ingredient of Tame-Said to prevent premature degradation of the active and to control the release rate of the active (Holme et al., column 4, lines 60-67).

Regarding claim 15, Holme et al. teach that the confectionary may be hard-boiled (column 12, line 21). It would have been prima facie obvious to hard-boil the lozenge because this is a known method of making a confectionary in the dentifrice art with predictable results (Holme et al., column 12, lines 1-30).

5. **Claims 11, 14 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tame-Said (abstract, WO 97/19668) (pub. June 5, 1997) in view of Bauman (US 3,928,618) (issued Dec. 23, 1975) as applied to claims 1, 3-4, 6, 8, 11-13 and 22 above, and further in view of Majeti et al. (US 6,682,722) (filed Sept. 3, 2002).**

The combination of Tame-Said and Bauman teach each limitation of claims 1 and 11 but fail to teach that the lozenge comprises urea. Majeti et al. cure this deficiency.

Regarding claims 11, 14 and 26, Majeti et al. teach oral care compositions for whitening of teeth (abstract) wherein the composition may be a lozenge (claim 9). Majeti et al. further teach that the oral care composition may comprise urea peroxide present at 5.5% (column 19, example 4, IV G).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Tame-Said and Bauman with those of Majeti et al. to incorporate urea peroxide into the composition.

One would have been motivated to do so because Bauman teaches that the lozenge may comprise whitening agents and Majeti et al. teach that urea peroxide is a tooth bleaching agent.

Regarding claims 27-29, Majeti et al. teach that the oral care composition may comprise urea peroxide as a bleaching agent from about 0.1% to about 20.0% (claim 13). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed ranges lie inside the range disclosed by Majeti et al. and are therefore prima facie obvious.

6. Claims 1, 3-4 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp (JP 01-172315) (pub. July 7, 1989) in view of Wolkoff et al. (US 3,511,914) (issued May 12, 1970).

Regarding claims 1, 3-4, 22-23, Lion Corp teaches a chewing gum comprising calcium pyrophosphate present at 2.0% by weight (example 7). The gum base and powder sugar make up 80% of the composition, resulting in more than 75% solids (example 7). Lion Corp teaches that the composition may be a gum or troche (lozenge) and may be used to improve the whiteness of the tooth (p. 1). However, Lion Corp fails to teach a base for a lozenge. Wolkoff et al. cure this deficiency.

Wolkoff et al. teach a vehicle for lozenges that has a water solubility which provides for a gradual dissolution in mouth fluids and is chemically and physically compatible with medicaments commonly employed in buccal formulations (abstract and

column 1, line 65 to column 2, line 13). The essential vehicle component is at least about 40% by weight of polyethylene glycol polymers having an average molecular weight of about 1,500 to about 20,000 (column 2, lines 60-66).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Lion Corp with those of Wolkoff et al. to have substituted the lozenge base of Wolkoff et al. for the gum base of Lion Corp. One would have been motivated to do so because Lion Corp teaches that the composition may be a gum or lozenge and Wolkoff et al. teach a lozenge base that is chemically and physically compatible with medicaments commonly employed in buccal formulations.

5. **Claims 5, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp (JP 01-172315) (pub. July 7, 1989) in view of Wolkoff et al. (US 3,511,914) (issued May 12, 1970) as applied to claims 1, 3-4 and 22-23 above, and further in view of Holme et al. (US 6,685,916) (filed Oct. 31, 2002.**

The combination of Lion Corp and Wolkoff et al. teach each limitation of claim 1 but fail to teach that the tablet comprise may be sugarless, comprises an encapsulated agent, or is in the form of a hard-boiled lozenge. Holme et al. cure these deficiencies.

Regarding claim 5, Holme et al. teach a composition for removing stains from dental surfaces. The composition may be a confectionary including lozenges (column 3, lines 47-53). The sweetener used in the confectionary may comprise sugar or be sugarless and instead use sugarless sweeteners such as sorbitol, mannitol, xylitol and maltitol (column 10, lines 33-41 and column 12, lines 9-15).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Lion Corp and Wolkoff et al. with those of Holme et al. to substitute sugarless sweetener for sugar in the composition. One would have been motivated to do so because using sugarless sweeteners reduces the amount of calories in the lozenge and does not contribute to the formation of dental plaque.

Regarding claim 10, Holme et al. teach that the composition may comprise encapsulated peroxide (claims 1 and 27). The peroxide is the active ingredient in the composition (abstract). It would have been prima facie obvious to a person of of ordinary skill in the art at the time of the invention to have encapsulated the active ingredient of Lion Corp to prevent premature degradation of the active and to control the release rate of the active (Holme et al., column 4, lines 60-67).

Regarding claim 15, Holme et al. teach that the confectionary may be hard-boiled (column 12, line 21). It would have been prima facie obvious to hard-boil the lozenge because this is a known method of making a confectionary in the dentifrice art with predictable results (Holme et al., column 12, lines 1-30).

7. Claims 6-9, 11, 14 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp (JP 01-172315) (pub. July 7, 1989) in view of Wolkoff et al. (US 3,511,914) (issued May 12, 1970) as applied to claims 1, 3-4 and 22-23 above, and further in view of Majeti et al. (US 6,682,722) (filed Sept. 3, 2002).

The combination of Lion Corp and Wolkoff et al. teach each limitation of claims 1, 3-4 and 22-23. However, they fail to teach that the composition may comprise sodium

bicarbonate as an additional tooth whitening agent of that the composition may comprise urea peroxide. Majeti et al. cure these deficiencies.

Regarding claims 6-9, 11, 14 and 24-25, Majeti et al. teach oral care compositions for whitening of teeth (abstract) wherein the composition may be a lozenge (claim 9). The composition may comprise an alkali metal bicarbonate salt, preferably sodium bicarbonate, present from about 0.5% to about 5% (column 15, lines 42-51). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed ranges overlap or lie inside the ranges disclosed by Majeti et al. and are therefore prima facie obvious.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Lion Corp as and Wolkoff et al. with those of Majeti et al. to incorporate sodium bicarbonate into the composition. One would have been motivated to do so because Lion Corp teaches that the composition may whiten teeth and sodium bicarbonate (baking soda) is a tooth whitening agent. MPEP 2144.06 states that "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art" quoting *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Regarding claims 11, 14 and 26, Majeti et al. teach that the oral care composition may comprise urea peroxide present at 5.5% as a bleaching agent (column 19, example 4, IV G). It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Lion Corp as and Wolkoff et al. with those of Majeti et al. to incorporate urea peroxide into the composition. One would have been motivated to do so because Lion Corp teaches that the composition may whiten teeth and urea peroxide is a bleaching agent. MPEP 2144.06 states that "[i]t is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art" quoting *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Regarding claims 27-29, Majeti et al. teach that the oral care composition may comprise urea peroxide as a bleaching agent from about 0.1% to about 20.0% (claim 13). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed ranges overlap or lie inside the ranges disclosed by Majeti et al. and are therefore prima facie obvious.

8. Claims 5 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lion Corp (JP 01-172315) (pub. July 7, 1989) in view of Wolkoff

et al. (US 3,511,914) (issued May 12, 1970) as applied to claims 1, 3-4 and 22-23 above, and further in view of Ning et al. (US 6,703,000) (filed May 15, 2002).

The combination of Lion Corp and Wolkoff et al. teach each limitation of claims 1, 3-4 and 22-23. However, they fail to teach that the composition may comprise Vitamin C. Ning. et al. cure these deficiencies.

Regarding claims 5 and 12-13, Ning et al. teach a confectionary composition comprising oral care actives (abstract) that is sugar-free (column 1, line 19). The composition may further comprise nutrients to improve the condition of the oral cavity, including vitamins such as Vitamin C (column 15, lines 5-19).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Lion Corp as and Wolkoff et al. with those of Ning et al. to incorporate Vitamin C into the composition and to use a sugarless sweetener instead of sugar. One would have been motivated to do so to improve the condition of the oral cavity and to reduce plaque formation.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./
Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611